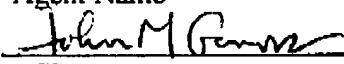


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Cotton et al.
Serial No. : 10/672,936
Filed : 25 September 2003
For : NOVEL FORM OF S-OMEPRAZOLE
Examiner : Aulakh, Charanjit
Group Art Unit : 1625

RECEIVED
CENTRAL FAX CENTER
JAN 16 2007

| | |
|--|-------------------|
| CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. 1.8 | |
| I hereby certify that this paper is being facsimile-transmitted to the U.S. Patent and Trademark Office on 16 January 2007 at the facsimile number <u>571-273-8300</u> . | |
| John M. Genova | 32,224 |
| Agent Name | PTO Reg. No. |
|  | 16 January 2007 |
| Signature | Date of Signature |

MAIL STOP APPEAL BRIEF – PATENTS**10 PAGES**

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

BRIEF FOR APPELLANT

Sir:

Applicants appeal the final rejection, mailed 10 August 2006, of claims 1 and 2. A Notice of Appeal was mailed on 8 December 2006. The Commissioner is authorized to charge any fee due in connection with this appeal to Deposit Account No. 23-1703.

USSN 10/672,936, filed 25 September 2003
Attorney Docket No.: 110326-0502
Page 2 of 10

I. REAL PARTY IN INTEREST

The real party in interest is the assignee: AstraZeneca AB (Assignment at Reel 010098, Frame 0174; Change of Name at Reel 012647/0602).

II. RELATED APPEALS AND INTERFERENCES

No related appeals or interferences are pending. However, there is a pending patent litigation in which the grandparent of the referenced application, i.e., US 6,369,085 (the "'085 patent"), is one of the patents-in-suit. The issue involving the '085 patent is patent infringement.

III. STATUS OF CLAIMS

The original application contained 16 claims, i.e., claims 1-16. By a Preliminary Amendment filed concurrently with the application, claims 2 and 14 were amended, claims 3-13, 15 and 16 were canceled and new claims 17 and 18 were added. Therefore, upon entry of the Preliminary Amendment and prior to any substantive examination of the claims, claims 1, 2, 14, 17 and 18 were pending.

Claims 1, 2, 14, 17 and 18 were rejected twice and a first final Office action issued 29 April 2005. In response to the first final Office action, a Request for Continued Examination ("RCE") and an Amendment were filed 28 October 2005. Subsequent to the RCE, the claims were rejected in a non-final Office action mailed 21 November 2005. Claims 14, 17 and 18 were canceled in the response to the non-final Office Action, thus leaving compounds claims 1 and 2 as the only pending claims, which remained rejected in a second final Office action, mailed 10 August 2006.

The final rejection of claims 1 and 2 is appealed.

IV. STATUS OF AMENDMENTS

No amendment has been filed subsequent to the second final Office action of 10 August 2006.

V. SUMMARY OF THE INVENTION

Esomeprazole (S-omeprazole) is the (-)-enantiomer of 5-methoxy-2-[[[(4-methoxy-3,5-dimethyl-2-pyridinyl)-methyl]sulfinyl]-1H-benzimidazole [0001].

The claimed invention is directed to the magnesium salt of S-omeprazole trihydrate [0001]. At the time the claimed invention was made, it was not known that the magnesium salt of S-omeprazole occurs in a number of structurally different forms [0011]. The compound of the invention is advantageous because it is more stable than the corresponding magnesium salt compounds of S-omeprazole in the prior art and, therefore, it is easier to handle and store [0012].

VI. THE GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1 and 2 of the subject application claim the same invention as claims 1 and 2 of the grandparent '085 patent and, therefore, are properly rejected under 35 U.S.C. §101 for statutory double patenting?

VII. ARGUMENT

A proper rejection under 35 U.S.C. §101 for statutory double patenting requires a determination that the same invention is being claimed twice. *In re Vogel*, 422 F.2d 438, 441 (Fed. Cir. 1970). Such a determination hinges upon the scope of the claims in question. *Id.* at 441; *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1280 (Fed. Cir. 1992). If the claimed inventions are identical in scope, the proper rejection is under 35 U.S.C. §101. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 197 (1984).

Although the specification is the primary basis for construing the claims, the prosecution history is also an important resource in ascertaining the scope and meaning of the claims. *Phillips v. AWH Corporation*, 415 F.3d 1303, 1317 (Fed. Cir. 2005). With specific regard to the value of the prosecution history to claim construction, the *Phillips* court emphasized that the prosecution history, like the specification, provides evidence of how the PTO and the applicant understood the patent. *Id.* at 1317.

In the pending application, there is no evidence that the Examiner considered the prosecution history of the '085 patent to determine the scope of claims 1 and 2 of the cited '085 patent in relation to claims 1 and 2 of the subject application. Rather, the §101 rejection of record is simply conclusory as suggested by the Examiner's unsupported statement that the "instant claims as well as the claims of the cited patent are identical" (See final Office action, mailed 10 August 2006).

In view of *Phillips*, it is respectfully submitted that the prosecution history of the '085 patent must first be consulted to determine how the PTO understood claims 1 and 2 of the '085 patent without which there cannot be a fair and just determination whether claims 1 and 2 of the subject application claim the same invention.

A. Prosecution history of claims 1 and 2 of the '085 patent

This appeal is concerned solely with the propriety of the rejection of compound claims 1 and 2 under 35 U.S.C. §101 for statutory double patenting in view of compound claims 1 and 2 of the grandparent '085 patent.

The '085 patent matured from U.S. Patent Application Serial No. 09/077,719 (the "'719 application"). By a Preliminary Amendment filed 12 November 1999, original compound claims 1-3 of the '719 application were amended as follows:

1. (Original) The magnesium salt of S-omeprazole trihydrate.
2. (Amended) The magnesium salt of S-omeprazole trihydrate according to claim 1, wherein the compound is in a characterized by being highly crystalline form.
3. (Amended) The magnesium salt of S-omeprazole trihydrate according to claim 1, wherein the compound is characterized by the following major peaks in its X-ray diffractogram: [.]

[continued]

| d-value / Å | Relative Intensity |
|-------------|--------------------|
| 2.67 | m |
| 2.79 | m |
| 3.27 | m |
| 3.52 | s |
| 3.82 | s |
| 3.96 | vs |
| 4.14 | m |
| 5.2 | m |
| 5.6 | m |
| 6.7 | vs |
| 6.9 | s |
| 8.3 | w |
| 16.6 | vs |

In a non-final Office action mailed 27 November 2000, the claims of the '719 application, including claims 1, 3, were rejected for obviousness under 35 U.S.C. §103 and for obviousness-type double patenting in view of several cited references. The Examiner alleged that the cited references disclose some form of a magnesium salt of omeprazole without specifying the water content. Therefore, according to the Examiner, the differences between the claimed invention and the cited references were the recitation of the (-)-enantiomer and trihydrate form. None of the dependent claims were objected to under 37 C.F.R. §1.75(c) as being an improper dependent claim for failing to further limit the subject matter of a previous claim.

As part of the response to the Office action, a declaration under 35 U.S.C. §1.132 was filed 4 May 2001. The declaration was submitted to show that the claimed magnesium salt of S-omeprazole trihydrate is unexpectedly and advantageously more stable than the cited and closest known prior art, i.e., the magnesium salt of S-omeprazole dihydrate.

Except for claim 3, the Examiner maintained the §103 and obviousness-type double patenting rejections of record in the subsequent Office action mailed 5 July 2001. With specific regard to claim 3, the Examiner stated:

3. Claims 1, 2, 4, 14, 16-17 are again rejected under 35 USC 103 as being unpatentable over the art of record for reasons of record. Applicants' declaration has been carefully considered. However, the result only applies to hydrate having the specific X-ray powder

diffraction value as listed in claim 3. Embracing the limitation of claim 3 into claim 1 would overcome this rejection.

4. Claims 1, 2, 4, 14, 16-17 are again rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over the patents of record for reasons of record. Embracing claim 3 into claim 1 would overcome this rejection.

5. Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In the Amendment filed 18 September 2001, claim 3 was canceled and claim 1 was amended as follows:

1. (Amended) The magnesium salt of S-omeprazole trihydrate, wherein the compound is characterized by the following major peaks in its X-ray diffractogram:

| d-value / Å | Relative Intensity |
|-------------|--------------------|
| 2.67 | m |
| 2.79 | m |
| 3.27 | m |
| 3.52 | s |
| 3.82 | s |
| 3.96 | vs |
| 4.14 | m |
| 5.2 | m |
| 5.6 | m |
| 6.7 | vs |
| 6.9 | s |
| 8.3 | w |
| 16.6 | vs |

The next action was a Notice of Allowance which issued 16 November 2001.

USSN 10/672,936, filed 25 September 2003
Attorney Docket No.: 110326-0502
Page 7 of 10

B. Prosecution history of claims 1 and 2 of the pending application

Claims 1 and 2 of the subject application correspond to *original* claims 1 and 2, respectively, of the '719 application.

Claims 1 and 2 of the subject application are rejected under 35 U.S.C. §101 for statutory double patenting in view of claims 1 and 2 of the '085 patent. It is alleged that there is no difference in scope between claims 1 and 2 of the subject application and claims 1 and 2 of the '085 patent since both sets of claims are identical and directed to the magnesium salt of S-omeprazole trihydrate.

C. Pending claims 1 and 2 are different in scope than claims 1 and 2 of the '085 patent.

Although the claims of the '719 application were rejected for prior art reasons, the claims of that application were never objected to for formal reason under 37 C.F.R. §1.75(c) which provides that:

One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application.

Thus, the prosecution history of the '085 patent establishes that the PTO understood original claim 3 of the '719 application reciting specific X-ray powder diffraction values to be a proper dependent claim referring back to and further limiting claim 1 directed to the magnesium salt of S-omeprazole trihydrate. The fact that claim 3 was not objected to under 35 C.F.R. §1.75(c) is especially noteworthy in view of recent Federal Circuit decisions stating that an applicant must also satisfy the formal requirements of 35 U.S.C. §112, ¶4, before obtaining a patent. *Pfizer Inc. v. Ranbaxy Laboratories Ltd.*, 457 F.3d 1284, 1292 (Fed. Cir. 2006); *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006). Therefore, the Examiner's present request for evidence showing that the peaks in X-ray diffractogram of the pending claims are different from the peaks recited by claim 1 of the '085 patent is both superfluous and inconsistent in view of the PTO's understanding that claim 3 of the '719 application contained a reference to claim 1 and specified a further limitation in satisfaction of 35 U.S.C. §112, ¶4. Had this not been the case, §608.01(n) of the Manual of Patent Examining Procedure provides that claim 3 should have been objected to under 37 C.F.R. §1.75(c) for failing to further limit the subject matter of a previous claim.

USSN 10/672,936, filed 25 September 2003
Attorney Docket No.: 110326-0502
Page 8 of 10

Furthermore, although the Examiner was persuaded by the comparative data in the §1.132 declaration showing that the claimed magnesium salt of S-omeprazole trihydrate is unexpectedly and advantageously more stable than the cited and closest known prior art, i.e., the Examiner stated that "the result only applies to hydrate having the specific X-ray powder diffraction value as listed in claim 3". Having stated that the comparative data set forth in the declaration under 37 C.F.R. §1.132 relates only to claim 3, the Examiner indicated that "[e]mbracing the limitations of claim 3 into claim 1" would overcome the prior art rejections. In the same Office action, the Examiner stated that, "[c]laim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." (Office Action, mailed 5 July 2001).

The quoted statements from the prosecution history of the '085 patent evidence the PTO's position and how the Examiner understood the claimed invention. Specifically, the Examiner understood there to be a difference in scope between original claim 1 directed to the magnesium salt of S-omeprazole trihydrate and original claim 3 referring back to and further limiting claim 1. To advance the '719 application to allowance and to enjoy the benefits conferred by a U.S. patent for allowable subject matter, claim 1 of the '719 application was amended to recite the X-ray powder diffraction values of claim 3 which was then canceled. The §103 and obviousness-type double patenting rejections were withdrawn and the '085 patent was granted.

Since it was the PTO's position that original claim 3 of the '719 application referred back to and further limited the subject matter of claim 1 of the '719 application in satisfaction of 35 U.S.C. §112, ¶4, and the related regulation 37 C.F.R. §1.75(c), then for the same reason claim 1 of the '085 patent must be limited or narrower in scope than claim 1 of the subject application. The PTO cannot now change its position since Applicants previously relied on the PTO and amended the claims accordingly.

USSN 10/672,936, filed 25 September 2003
Attorney Docket No.: 110326-0502
Page 9 of 10

CONCLUSION

A court has the power and obligation to construe as a matter of law the meaning of the language used in the patent claims. *Markman v. Westview Instr., Inc.*, 52 F.3d 967 (Fed. Cir. 1995). The prosecution history is relevant to a proper interpretation of the claims. *Id.* at 980.

The prosecution history of the '085 patent evidences that the PTO understood the scope of original claim 1 directed to the magnesium salt of S-omeprazole trihydrate to differ from that of original claim 3 reciting specific X-ray powder diffraction values. It is submitted that the examination of the invention of original claim 1 of the '719 application in the subject application does not negate the precedent established by the PTO: the scope of original claim 3, now claim 1 of the '085 patent, is different from original claim 1 of the '719 application. *A fortiori*, the scope of original claim 3, now claim 1 of the '085 patent, cannot now be considered identical to that of pending claim 1 merely because patentability of the claimed invention is the subject of a different application.

A contrary conclusion such as the §101 rejection of record derogates the "indisputable public record consisting of the claims, the specification and the prosecution history", thereby undermining the public notice function of patents. *Phillips*, 415 F.3d 1303 at 1319; quoting *Southwall Techs. Inc. v. Cardinal IG Co.* 54 F.3d 1570, 1578 (Fed. Cir. 1995). Withdrawal of the §101 rejection is requested.

Attached to this Appeal Brief is an appendix containing a copy of the claims involved in the appeal, i.e., claims 1 and 2.

Respectfully submitted,

Dated: 16 January 2007



John M. Genova
Reg. No. 32,224

Customer No. 07470
(212) 819-8832

FROM W&C LLP 19TH FL.

(TUE) 1.16'07 15:18/ST. 15:15/NO. 4260454271 P 10

USSN 10/672,936, filed 25 September 2003
Attorney Docket No.: 110326-0502
Page 10 of 10

CLAIMS APPENDIX

U.S. Patent Application Serial No. 09/029, 403

1. The magnesium salt of *S*-omeprazole trihydrate.
2. The magnesium salt of *S*-omeprazole trihydrate according to claim 1, wherein the compound is in a highly crystalline form.